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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/737,904	11/20/1996	IRWIN J. GRIFFITH	IMI040CP3	5732
959	7590	04/21/2004	EXAMINER	
LAHIVE & COCKFIELD, LLP. 28 STATE STREET BOSTON, MA 02109			SCHWADRON, RONALD B	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 04/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/737,904	GRIFFITH ET AL.	
	Examiner	Art Unit	
	Ron Schwadron, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 10-13 and 21-23 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 10-13, 21-23 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

1. Claims 1-3,10-13,21-23 are under consideration.

RESPONSE TO APPLICANTS ARGUMENTS

2. The amendment filed 10/21/2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows.

The addition of the phrase "The entire contents of the above-referenced applications are incorporated herein by reference." in page 1, line 3 of the specification. This language lacks support in the specification as originally filed.

Applicant is required to cancel the new matter in the reply to this Office Action.

3. Regarding the claim to priority to application 08/106016 in page 1 of the specification and benefit claims under 35 U.S.C. 120, the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications.

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-3,10-13,21-23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 5,710,126. Although the conflicting claims are not identical, they are not patentably distinct from each other because while the two sets of claims differ in scope, the elected species of peptides in the instant application are recited in the claims of U.S. Patent No. 5,710,126. Regarding the various functional limitations recited in the claims, said limitations appear to be inherent properties of the specific peptides recited in the claims. Regarding the various manipulations recited in the claims (eg. change sequence to increase solubility), said manipulations were well known in the art (see prior art disclosed in specification, page 12). Therefore, the two sets of claims under consideration in this rejection would have been prima facie obvious in view of each other to one of ordinary skill in the art at the time the invention was made.

Applicant has indicated that a terminal disclaimer would be filed upon indication of allowable subject matter.

6. The rejection of claims 1-6,9-15,21,23,26-28,38-41 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons elaborated in the previous Office Action is withdrawn in view of the amended claims and the cancellation of particular previously pending claims recited in this rejection.

7. The rejection of claims 21-23,26 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for the reasons elaborated in the previous Office Action is withdrawn in view of applicants arguments and the cancellation of claim 26.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. The rejection of claims 1-6,9,11-15,21-23,26-28 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons elaborated in the previous Office Action is withdrawn in view of the amended claims and the cancellation of particular previously pending claims recited in this rejection.

10. Claims 12,13,23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 12 and 13 are indefinite in that they depend from claims 1 or 2 which read on peptides consisting of the recited amino acid sequences (and are therefore "closed" and do not encompass peptides with amino acid additions or substitutions) whilst the solubility modified peptides of claims 12 and 13 encompass peptides with amino acid additions or substitutions (as per the specification, page 12).

11. The rejection of claims 1-6,9,12-15,21-23,26-28 as rejected under 35 U.S.C. 102(b) as being anticipated by Griffith et al. (WO 95/06728) is withdrawn in view of the amended claims, applicants arguments and the cancellation of particular previously pending claims recited in this rejection.

12. The rejection of claims 1,3-5,12-15,21,23,26-28,38-41 as rejected under 35 U.S.C. 102(b) as being anticipated by Singh et al. (US Patent 5,721,119)) is withdrawn in view of the amended claims, applicants arguments and the cancellation of particular previously pending claims recited in this rejection.

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 1-3,10-13,21,23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Singh et al. (US Patent 5,721,119) in view of Perez et al. Singh et al teach the amino acid sequence of Lol p Ib.1 (see SEQ. ID. no. 1) wherein said sequence contains LPIX-4. Singh et al. teach that the peptides derived from Lol p Ib.1 can be modified to improve solubility (see column 145, second paragraph). Singh et al. teach a composition containing said peptide and a pharmaceutically acceptable carrier (see column 24). Singh et al. do not a peptide identical in length to LPIX-4. Perez et al. teach that a collection of 20mer peptides can be made from a different rye grass allergen (Lol p I) in order to determine which portions of the molecule contain T cell epitopes (see page 16212, second column. last paragraph, continued on next page). The peptides are 20mers made starting with the first amino acid of the allergen wherein the following 20mer overlaps by 10 amino acids. The peptides in the instant application (including LPIX-4) were made using the same strategy with a different Lol antigen. A routineer would have used the strategy taught by Perez et al. in order to produce a collection of peptides to identify the T cell epitopes in Lol p Ib.1. Singh et al. teach that it is desirable to identify the T cell epitopes of Lol p Ib.1 and that this information would be ascertained by screening fragments for reactivity with T cells (see columns 9 and 10). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Singh et al teach the amino acid sequence of Lol p Ib.1 (see SEQ. ID. no. 1) wherein said sequence contains LPIX-4 whilst Perez et al. teach that a collection of

20mer peptides can be made from a rye grass allergen in order to determine which portions of the molecule contain T cell epitopes. The 20mer collection of Lol p Ib.1 peptides would include LPIX-4 and other peptides recited in the claims and would therefore contain peptides with the functional characteristics recited in claims 3,10 and 11 because the peptides are the same as those recited in the claims. One of ordinary skill in the art would have been motivated to do the aforementioned because a routineer would have used the strategy taught by Perez et al. in order to produce a collection of peptides to identify the T cell epitopes in of Lol p Ib.1, whilst Singh et al. teach that it is desirable to identify the T cell epitopes of Lol p Ib.1, and that this information would be ascertained by screening fragments for reactivity with T cells.

Regarding applicants comments, the LPIX-4 peptide is rendered obvious for the reasons elaborated in the instant rejection.

15. No claimed is allowed.

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached Monday to Thursday from 7:30am to 6:00pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached 571 272 0841. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP 1800-1600

Ron Schwadron, Ph.D.

Primary Examiner

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